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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,123	12/29/1998	ROBERT A. RAY	6328-21	3601

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EXAMINER
CROSS, LATOYA I

ART UNIT	PAPER NUMBER
1743	17

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

TG-17

Office Action Summary

Application No.	Applicant(s)	
09/222,123	Ray et al	
Examiner	Art Unit	
CROSS	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 9-17-2001

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-12 and 19-42 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-12 and 19-42 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on September 17, 2001 and entered as Paper No. 16. Claims 1-12 and 19-42 are pending. Claims 27-42 were newly added.

Withdrawal of Rejections from Previous Office Action

The rejection of claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 under 35 USC 102 is withdrawn in view of Applicants' amendment to the claim to incorporate "a dried biological sample" into the apparatus claim.

Claim Rejections - 35 USC □ 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent 5,609,160 to Bahl et al (hereinafter Bahl et al '160).

Bahl et al '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28) which allows the oral sample to be extracted during centrifugation. At col. 4, lines 8-14, Bahl et al '160 disclose that a portion of the absorbent pad is treated with a chemical

indicator (dye) such that when sufficient fluid is taken up by the pad, a change in color occurs. Also provided are a package for return of the sample by mail, and an identification card (90) containing information for identifying the sample. See figures 1 and 10.

It is noted that Bahl et al '160 does not explicitly teach that the apertures "facilitate removal of a portion of the collection pad", however, Applicants' define the means for performing this function as apertures through the collection end of the device. MPEP 2114 states that "means plus function limitations are met by structures which are equivalent to the corresponding structures recited in the specification", citing *In re Ruskin*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965).

It is also noted that "drying the sample" is not disclosed by Bahl et al '160, however, this is Applicants' intended use which is accorded no patentable weight since the claims are directed to a device which is defined by its structure and not function. See MPEP 2114.

Bahl et al'160 do not specifically teach a "dried biological sample". However, since this limitation regards the material worked on by the apparatus. MPEP 2115 states that "expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability", citing *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Therefore, although Applicants' may have included this in their claims as a limitation, it does not impart patentability to the claimed invention.

It would have been obvious to one of ordinary skill in the art to make a sample collection device having a handle, collection pad and an aperture suitable for aiding the removal of a portion of the collection pad.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 U.S.C. 103(a) in view of the teachings of Bahl et al '160.

3. Claims 5, 11, 12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160 and further in view of US patent 6,165,416 to Chandler (hereinafter referred to as Chandler '416).

With respect to the above-mentioned claims, Applicants claim that the device uses glass fiber as an absorbent material and has a plurality of collection pads and apertures.

Chandler '416 teaches a sample collection device comprising an elongated dipstick collection member having an absorbent matrix. The absorbent matrix is disclosed as being any of the conventional absorbent materials including cellulose, nitrocellulose, glass fiber and sintered fiber (col. 3, lines 58-65). Since such materials are well known in the art, it would have been obvious to one of ordinary skill in the art to use any of the materials in the collection device of Bahl et al '160.

With respect to the device containing a plurality of apertures and collection pads, it would have been obvious to one of ordinary skill in the art to incorporate multiple

apertures and collection pads so that multiples tests or assays may be performed on a single support.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 U.S.C. 103 in view of the teachings of Bahl et al '160 and Chandler '416.

4. Claims 2, 3, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160, and further in view of US Patent 5,656,503 to May et al (hereinafter May et al '503).

With respect to the above-mentioned claims, Applicants' invention is directed to the collection pad containing urine and albumin. With respect to claims 27-42, Applicants' invention is further directed to the use of polyvinyl alcohol as the absorbent material.

May et al '503 teaches a test device for detecting analytes in biological samples, such as urine, comprising a hollow casing containing a porous carrier and a bibulous receiving member. At col. 9, lines 45-48, May et al '503 teaches the use of blocking reagents such as BSA (albumin) and polyvinyl alcohol for blocking excess binding sites in each zone of the test device.

Thus, it would have been obvious to one of ordinary skill in the art to incorporate such reagents into the device of Bahl et al '160 where the blocking of such binding sites is necessary.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Bahl et al '160 and May et al '503

Response to Arguments

5. The following is in response to Applicants' remarks filed on September 17, 2001.

Applicants argue, with respect to the rejections given in the previous Office Action, that 1) there is no disclosure of a "dried biological sample" in the cited references and 2) the collection pads of May et al are "treated" with polyvinyl alcohol whereas the collection pads of the instant invention "comprise" polyvinyl alcohol.

With respect to the "dried biological sample", this limitation does not impart patentability to the claimed invention, as explained above. The claimed structure of the device remains to be deemed obvious in view of Bahl et al.

With respect to the polyvinyl alcohol disclosed by May et al, it is the position of the Examiner that there is no difference in an absorbent pad that "comprises" PVA and one that is "treated" with PVA. In both instances the PVA is comprised in the absorbent pad.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC

November 29, 2001

Jill Warden
Supervisory Patent Examiner
Technology Center 1700